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PATENT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Cioca, et al.

Serial No.: 09/838,649

Group Art Unit: 1617

Filed: April 19, 2001

Examiner: Wells, Lauren Q.

For: Stable Antimicrobials in Structured Water

**RESPONSE PURSUANT TO 37 CFR 1.111 - Remarks**

The pending claims of the present invention are rejected for being obvious in view of Cioca et al. (U.S. Patent No. 6,139,855; hereinafter "the '855 reference") and Beerse et al. (U.S. Patent No. 6,217,887) and in view of the '855 reference and Stroud et al. (U.S. Patent No. 6,231,837). The Examiner finds that an antimicrobial agent such as silver ions added to structured water in the prior art will result in a product where silver ions are integrated within the cluster structure of the structured water despite the data that was submitted with Applicants previous Response of July 21, 2004 in the Manzatu Declaration demonstrating otherwise. Specifically, with respect to the data in the Manzatu Declaration, the Examiner finds that the data does not suggest that the present invention is different than compositions described in the '855 reference (U.S. Patent No. 6,139,855). Essentially, it is the Examiner's assertion that the Manzatu Declaration provides no data showing that the addition of antimicrobial agents to structured water would not result in the same agents being integrated into the structured water.

According to the Examiner, the '855 reference teaches I and S water characterized by a conductivity and pH within the ranges set forth in the present claims. However, unlike the present invention, as amended, the active in the '855 reference is added to I and S water. In Example II, at column 5, lines 36 to 37, of the '855 reference, it is indicated that "[c]affeine is added at a level to a series of different vehicles." Each of the vehicles in Example II is either deionized water or structured water. Therefore, the '855 reference does not teach or suggest that caffeine is added to feed water and processed to make structured water. A product by process claim differs from another product by process claim if the starting materials and the process are separate and distinct from one another and if a different product results. Because I and S water are formed from treated feed water, in the present invention, the antimicrobial is added to feed water composed of deionized water with a particular cluster structure stabilizing ionic component. This is not disclosed by the '855 reference. In the present specification, the feed water for cluster stabilization in the present invention is provided at page 7, lines 16 to 25. The feed water for cluster stabilization in the present invention has a pH of about 6.0 to 6.4 and a C ( $\mu\text{S}/\text{cm}$ ) of about 470 to 520. This is in contrast with the '855 starting water which is taught in Claim 1 of the '855 reference as having a pH of about 7 to 7.5 and 250 to 450  $\mu\text{S}/\text{cm}$ .

The addition of active agents to structured water as taught in the '855 reference is different ~~than~~ the integration of antimicrobial agents within the cluster structure of structured water as described in ~~the~~ present invention both with respect to the starting materials and the product, and the data in the Declaration under 37 C.F.R. 1.132 by Mirela Ionita-Manzatu ("the Manzatu Declaration") demonstrates the difference ~~between~~ the two.

In the Manzatu Declaration, the results of the study are described in paragraph 7, and they ~~show~~ that samples of structured water without the Tb marker (sample 1) and of structured water in solution (i.e., the Tb added to the structured water, sample 3) are substantially different than the sample having structured water prepared according to the present invention (i.e., the Tb integrated within the cluster structure of structured water, sample 2.) The substantial difference is demonstrated by the location of peaks on the spectral curves of each sample. Spectral analysis is a common analytical tool used to identify and determine the structure of unknown compounds. The Tb marker in this case marks the location of the Tb ion in each situation, one where Tb is added to structured water, and the other where Tb is integrated in the cluster structure of water to demonstrate the presence of the antimicrobial. This is explained in paragraph 6 of the Manzatu Declaration. Tb ions are capable of being detected by fluorescent emission spectral analysis, and it can be seen where they are located, either within the cluster or outside of the cluster.

Fluorescence spectroscopy is a type of electronic spectroscopy that is used to probe the structure of molecules. When molecules undergo electronic transitions, electrons move between orbitals. This movement changes the bonding patterns. The change in bond length often leads to a vibrational progression in the absorption spectrum of the molecule. Fluorescent spectral analysis can determine which vibrational modes are coupled to an electronic change. This methodology is explained in a paper taken from a Chem 434 course at the University of Alaska at Fairbanks, entitled "Benzene Ultraviolet Absorption and Fluorescence Spectroscopy: Elucidating the Geometric Changes Upon Excitation Through Isotopic Substitution and Quantum Chemistry Modeling" submitted herewith. Thus, fluorescent spectroscopy is a recognized analytical tool for assessing electronic changes as was the goal of the study presented in the Manzatu Declaration.

Referring back to the study in the Manzatu Declaration, three samples were analyzed: 1) samples of structured water without the Tb marker (sample 1); 2) samples of structured water in solution with the Tb marker (i.e., the Tb added to the structured water, sample; and 3) samples of the Tb integrated within the cluster structure of structured water, sample 2.) Both samples 1 and 3 had peaks located at about 416 nm indicating similar electronic arrangement. In contrast to these samples, sample 2 of the present invention had a peak at about 369 nm, thus, demonstrating an electronic change. In addition, sample 2 exhibited a reduction in peak intensity. Therefore, the Tb marker is shielded from fluorescence by being integrated within the cluster structure of structured water. This finding confirms that structured water of the present

invention having the Tb marker integrated in the cluster structure of structured water is not a mere solution of the Tb marker added to structured water. These results correlate with the behavior of the antimicrobial ions integrated within the cluster structure of the structured water of the present invention. Therefore, the antimicrobial agent integrated within the cluster structure of structured water in the present invention is not taught or suggested by the combination of the cited references adding an antimicrobial to structured water.

The Examiner has rejected Claims 1, 4, 5, 9, 11 to 12, 19 to 20, and 22 provisionally under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-5 of copending Application No. 10/183,819. Applicants acknowledge the provisional double patent rejection made by the Examiner. However, in light of the arguments set forth below, Applicants will make a terminal disclaimer, if necessary, in the event that allowable subject matter is indicated.

With respect to the integration of antimicrobial agents in the clusters of structured water in comparison with the integration of antioxidants, Applicants assert that it is surprising to find that the antimicrobial agents can be integrated. The claims of the present invention, as amended, are directed to two antimicrobial agents of the silver ion and the potassium sorbate which are integrated within the cluster structure of structured water. No new matter is added. As explained in the present specification, at page 6, lines 5 to 12, the characteristics of silver ions made it appear difficult if not impossible to incorporate in the clusters of structured water. Because of their large ionic radius, it was expected that there would not be enough room for them to replace the stabilizing ions, which have a smaller ionic radius. However, surprisingly it was found that potassium ion causes a perturbation in the clusters that opens a space sufficient for the large silver ion to enter into the clusters of the structured water. Therefore, the two antimicrobial agents have been found to work together in the integration of the silver ion into the clusters of the structured water and is therefore, a distinct and different system than the integration of an antioxidant in the cluster of structured water noted by the Examiner in copending Application No. 10/183,819.

The other combination of references cited against the present invention is Cioca et al. and Stroud et al., however, the same situation arises when making this combination as does with the previous combination of cited references. Therefore, because the combination of Cioca et al. ("the '855 reference") and Stroud et al. fails to remedy the defect of the primary reference (the '855 reference), Applicants assert that this combination of references also fails to render the present invention obvious. In the '855 reference, biological actives are only added to structured water as separate entities, one being added to the other. Further, there is no teaching or suggestion in the '855 reference of adding the biological active to the feed water having the pH of about 6.0 to 6.4 and a conductivity of about 470 to 520, and treating both the active and the specific feed water to integrate the antimicrobial in the cluster structure of the structured water. Therefore, the '855 reference in combination with any other reference that fails to remedy this defect will not render the present invention, as amended, obvious and a *prima facie* case of obviousness has not been

made. However, even if a *prima facie* case of obviousness could be made, the Manzatu Declaration demonstrates that the addition of an antimicrobial agent to structured water is substantially different than the integration of the antimicrobial agent within the cluster structure of structured water. As the claims of the present application, as amended, are believed to be in condition for allowance, issuance of a Notice of Allowance is respectfully solicited.

Respectfully submitted,

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